

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 8/30/2019

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EMED TECHNOLOGIES CORP., :
Plaintiff, :
:
-against- :
:
REPRO-MED SYSTEMS INC., :
Defendant. :
----- X

18 Civ. 5880 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Plaintiff EMED Technologies (“EMED”) alleges that Defendant Repro-Med Systems, Inc. (“RMS”) infringed United States Patent No. 9,808,576 (the “‘576 Patent”), titled “Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle.” The ‘576 patent relates to a device that sheaths a medical needle within a protective pair of folding wings during and after the removal of the needle from the patient’s skin. Defendant moves for summary judgment of non-infringement as to claims 1 through 3 of the ‘576 patent. For the reasons stated below, Defendant’s motion for summary judgment is granted.

I. BACKGROUND

The summary below is taken from the parties’ Rule 56.1 statements as well as the record before the Court.

The disputed ‘576 patent relates to a medical device that aids in the treatment of Primary Immunodeficiency Disease (“PIDD”). Individuals with PIDD require immunoglobulin (human plasma and antibodies) to lead normal lives. Immunoglobulin is commonly administered to patients in their homes through under-the-skin infusions, known as Subcutaneous Immunoglobulin (“SCIg”) therapy. In SCIg therapy, a mechanical infusion pump delivers the

immunoglobulin via plastic tubing and a subcutaneous needle. At issue here is the ‘576 patent, titled “Devices and Methods for Protecting a User from a Sharp Tip of a Medical Needle.”

The ‘576 patent was issued on November 7, 2017. Generally, the ‘576 patent discusses devices that have a pair of wings that open and close and are attached to a central body portion, as well as a medical needle located in that central body portion. When the wings are in the open position, the medical needle can be inserted at a patient treatment site. When the wings are in the closed position, the wings cover the medical needle such that the user is protected against accidental needle stick injury. The ‘576 patent specification discloses several types of structures to join a pair of wings together to protect a user from accidental needle stick. Claim 1 of the ‘576 patent describes:

A device for protecting a user from a sharp tip of a winged medical needle, the device comprising:

a central body portion;

. . . a mechanical fastener disposed on at least one wing of the pair of wings, the mechanical fastener configured to selectively attach the pair of wings together in the closed position with the medical needle positioned therebetween to protect against accidental needle stick injury from the sharp tip of the medical needle;

the mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align with at least one wing relative to the at least one other wing in the closed position (emphasis added).

Following a claim construction hearing on May 21, 2019, the Court construed the term “consisting of” as a “closed-ended term” such that the “mechanical fastener claim include[s] only (1) a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and (2) a mating portion along a perimeter of at least one other wing of the pair of wings.” *Emed Techs. Corp.*, No. 18 Civ. 5880, 2019 WL 2353030, at *4 (S.D.N.Y. June 4,

2019). At the hearing, the parties agreed that “‘a mating portion along a perimeter of at least one other wing of the pair of wings, and wherein the mating portion and the lip are configured to align the at least one wing relative to the at least one other wing in the closed position’ means ‘a mating portion along an outer boundary of at least one other wing of the pair of wings, and wherein the mating portion and the raised edge are designed to align the at least one wing relative to the at least one other wing in the closed position.’” *Id.* at *2.

EMED identifies forty-seven RMS needles under the brand name High Flo Subcutaneous Needle (the “accused products”) as infringing devices. Each of the accused products includes a unitary cast thermoplast structure having a housing that contains a portion of a bent medical needle and a pair of wings extending outwardly from, and on opposite sides of, the housing, such that the wings can move relative to the housing between a closed position and an open position. One wing has an outer section that includes a cylindrical plug projecting from the surface, and the other wing has a corresponding outer section that includes a socket for receiving the plug.

II. STANDARD

A. Summary Judgment

Summary judgment is appropriate where the record establishes “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). There is a genuine dispute as to a material fact “if the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986); *accord Nick’s Garage, Inc. v. Progressive Cas. Ins. Co.*, 875 F.3d 107, 113 (2d Cir. 2017). “Only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment. Factual disputes

that are irrelevant or unnecessary will not be counted.” *Liberty Lobby*, 477 U.S. at 248; *accord Saleem v. Corp. Transp. Grp., Ltd.*, 854 F.3d 131, 148 (2d Cir. 2017).

The court must construe the evidence in the light most favorable to the nonmoving party and must draw all reasonable inferences in favor of the nonmoving party. *Liberty Lobby*, 477 U.S. at 255; *accord Soto v. Gaudett*, 862 F.3d 148, 157 (2d Cir. 2017) (citations omitted). When the movant has properly supported its motion with evidentiary materials, the opposing party may only establish a genuine issue of fact by “citing to particular parts of materials in the record.” Fed. R. Civ. P. 56(c)(1)(A). “[A] party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment.” *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (alteration in original); *accord Rodriguez v. City of New York*, 291 F. Supp. 3d 396, 408 (S.D.N.Y. 2018).

B. Infringement

“An infringement analysis entails two steps. The first step is determining the meaning and scope of the patent claims asserted to be infringed. The second step is comparing the properly construed claims to the device accused of infringing.” *Duncan Parking Techs., Inc. v. IPS Grp., Inc.*, 914 F.3d 1347, 1360 (Fed. Cir. 2019). “To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly.” *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995); *accord E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1073 (Fed. Cir. 2019). This second step of the infringement analysis is a question of fact, and therefore summary judgment on a claim of literal infringement is appropriate “when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device.” *Mirror Worlds Techs., LLC v. Facebook, Inc.*, 320 F.

Supp. 3d 538, 543 (S.D.N.Y. 2018) (citing *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998)). “The patentee has the burden of proving infringement by a preponderance of the evidence.” *Duncan Parking Techs., Inc.*, 914 F.3d at 1360.

III. DISCUSSION

A. Literal Infringement

1. Step One: Claim Construction

On June 4, 2019, the Court completed the first step of determining the meaning and scope of the allegedly infringed claims and issued an order construing the disputed claim terms of the ‘576 patent. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc) (concluding that claim construction, the first step in infringement analysis, is an issue of law).

The claim construction order narrowed the scope of the mechanical fastener claim to include “only (1) a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and (2) a mating portion along a perimeter of at least one other wing of the pair of wings.” *Emed Techs. Corp.*, 2019 WL 2353030, at *4. Plaintiff argues that the Court’s construction of the mechanical fastener term did not necessarily preclude another mechanical fastener on the device. At issue here is whether the “comprising” language used in the preamble of the ‘576 patent allows the addition of a second mechanical fastener when “a” is used **before** the term “mechanical fastener” and “consisting of” is used in the body of the claim **after** the term mechanical fastener. It does not.

The prosecution history reveals that Plaintiff intentionally narrowed claim 1 of the ‘576 patent to preclude the addition of a second mechanical fastener akin to the plug and socket closure on RMS’s accused products. “The meaning of a term ‘must be considered in the context

of all the intrinsic evidence, including the claims, specification, and prosecution history.’”

Iridescent Networks, Inc. v. AT&T Mobility, LLC, No. 2018-1449, 2019 WL 3770833, at *4 (Fed. Cir. Aug. 12, 2019) (quoting *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013)). “The prosecution history, like the specification, provides evidence of how the U.S. Patent and Trademark Office and the inventor understood the patent.” *Id.* “[A]ny explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to ‘capture the scope of the actual invention’ that is disclosed, described, and patented.” *Id.* at *6; accord *Fenner Invs., Ltd. v. Celco P’ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015). The prosecution history “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*; see also *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (“The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution. . . . [This] ensures that claims are not construed one way in order to obtain their allowance and in a different way against accused infringers.”) (quotation marks and internal citations omitted).

Although the ‘576 patent specification broadly discloses several types of structures to join a pair of wings together to protect a user from accidental needle stick, the prosecution history reveals that Plaintiff specifically limited the mechanical fastener element to one consisting of only a “lip” and “mating portion.” The ‘576 patent claims priority from Plaintiff’s United States Patent No. 8,500,703 (the “‘703 patent”). During the prosecution of the ‘703 patent, Plaintiff amended the claims in the ‘703 patent application to overcome the rejection of

prior art as being obvious over patent 6,500,155 (“Sasso”), which included a cylindrical peg and socket to join the wings in a snap closure. As amended, the ‘703 application claimed:

[T]he mechanical fastener including a lip extending along at least a portion of the perimeter of at least one of the wings, and a recessed portion along a perimeter of at least the other one of the wings; and the recessed portion and the lip configured to engage with one another to selectively attach the pair of wings together with the medical needle positioned therebetween so as to protect a user from the sharp tip of the medical needle (emphasis added).

To distinguish the ‘703 fastener from Sasso’s peg and socket fastener, Plaintiff explained in its ‘703 patent application that “providing a mating contoured lip and recess around the perimeter of the wings serves a dual purpose: It simplifies the snapping process; and it makes it difficult for the needle to be pushed out of alignment, and thus, be moved out of the wings.” Plaintiff specified, “Among other things, the prior art Sasso reference does not teach or suggest a device including an engaging lip and mating recessed portion along the perimeters of the wings, as required by Applicant’s amended claim 1.” Plaintiff’s ‘703 application thus relied on the “lip and mating recessed portion along the perimeter of the wings” to differentiate its device from the prior art (Sasso).

During the prosecution of the ‘576 patent, the Examiner rejected Plaintiff’s claim for “the mechanical fastener including a mating portion” as obvious in light of a combination of two prior art references, Sasso and patent application 2010/0010451 to Kashmirian (“Kashmirian”) (emphasis added). The Examiner explained that Sasso disclosed all the elements of the ‘576 patent’s claim 1, except, instead of a mechanical fastener including a lip and a mating portion, Sasso disclosed a projecting cylindrical peg and socket to join the wings. Kashmirian disclosed a mechanical fastener including a lip and mating portion. Thus, as combined, Sasso and Kashmirian resulted in a device having a mechanical fastener with multiple closure mechanisms -- a peg and socket closure mechanism, as taught by Sasso, and a lip and mating portion closure

mechanism, as disclosed by Kashmirian. To overcome the prior art (Sasso and Kashmirian), the Examiner suggested that Plaintiff amend claim 1 “to specifically say the mechanical fastener consists of a lip or the mechanical fastener is only a lip” (emphasis added). Plaintiff subsequently adopted the Examiner’s recommendation and amended claim 1 to: “the mechanical fastener consisting of a lip extending along at least a portion of a perimeter of at least one wing of the pairs of wings,” replacing the “including” with “consisting of” (emphasis added). After Plaintiff amended the mechanical fastener element to replace “including” with “consisting of,” the patent was approved. Accordingly, the prosecution history shows that Plaintiff intentionally narrowed the scope of the mechanical fastener claim to include only (1) a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and (2) a mating portion along a perimeter of at least one other wing of the pair of wings, at the exclusion of other mechanical fastener elements, such as the peg and socket closure in Sasso.

Plaintiff argues that the use of “comprising” in the preamble necessarily means additional mechanical fasteners are allowed. *See Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016) (“[The] transitional term ‘comprising’ creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.”) (quotation marks omitted). Plaintiff contends that “[t]he use of consisting in the body limits the particular claimed mechanical fastener to the recited elements following the mechanical fastener and does not limit an entirely different mechanical fastener.” *See Multilayer Stretch Cling Film Holdings, Inc.*, 831 F.3d at 1358 (“Use of the transitional phrase ‘consisting of’ to set off a patent claim element creates a very strong presumption that that claim element is ‘closed’ and therefore ‘exclude[s] any elements, steps, or ingredients not specified in the claim.’”) (alteration in original). Here, the use of the word

“comprising” in the transitional phrase does not govern the construction of the mechanical fastener term. As discussed above and in the Court’s claim construction order, *Emed Techs. Corp.*, 2019 WL 2353030, at *4, the prosecution history and the claim’s use of the word “consisting of” makes clear that the mechanical fastener as claimed has only two elements -- (1) a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings, and (2) a mating portion along a perimeter of at least one other wing of the pair of wings -- and no additional mechanical fasteners are claimed. See *Digene Corp. v. Third Wave Techs., Inc.*, 323 F. App’x 902, 908-09 (Fed. Cir. 2009) (stating that “the district court permissibly found the prosecution history conclusive” in holding that the applicant narrowed the scope of the HPV DNA claimed during prosecution history such that the court properly construed “consists of all or a fragment of an HPV DNA” to mean “consists of all or a fragment of one HPV DNA that does not contain any other DNA,” despite the word “comprising” in the preamble).

Plaintiff argues that “[i]n *Digene*, the Federal Circuit clarified that a claim with the overall transitional phrase ‘comprising,’ containing a limitation with the transitional phrase ‘consisting of’ allowed for the addition of other elements to the overall claim.” Plaintiff misconstrues *Digene*. Although the *Digene* court repeated the rule of construction that “comprising” is an open-ended term, Plaintiff ignores that the court also explicitly stated that the transitional phrase “comprising” does not “open[] the individual elements limited by the term ‘consisting of.’” *Digene*, 323 F. App’x at 909. Thus, the court found that the clause following “consists of” could not be expanded to include DNA fragments other than those recited. *Id.* Here, “consisting of” limits the mechanical fastener term to the two elements recited after the term, and the prosecution history excludes the addition of other mechanical fasteners.

Plaintiff contends that its amendment to claim 1 of the ‘576 patent does not preclude a second mechanical fastener, as evidenced by its continuing application USSN 15/718,470, which contains the language: “the mechanical fastener including a lip extending along at least a portion of a perimeter of at least one wing of the pair of wings.” EMED, however, cannot rely on a later-filed “child” application (15/718,470) to establish that the “parent” patent (the ‘576 patent) is broader than what Plaintiff ultimately claimed. “[T]here is no principle of patent law that the scope of a surrender of subject matter during prosecution is limited to what is absolutely necessary to avoid a prior art reference that was the basis for an examiner’s rejection.” *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356, 1361 (Fed. Cir. 2005). “To the contrary, it frequently happens that patentees surrender more through amendment than may have been absolutely necessary to avoid particular prior art. In such cases, we have held the patentees to the scope of what they ultimately claim, and we have not allowed them to assert that claims should be interpreted as if they had surrendered only what they had to.” *Id.* at 1361-62; *accord Ajinomoto Co. v. Int’l Trade Comm’n*, No. 2018-1590, 2019 WL 3558560, at *5 (Fed. Cir. Aug. 6, 2019) (“A patentee must ‘be held to what he declares during the prosecution of his patent,’ because a contrary rule would undermine ‘[t]he public notice function of a patent.’”) (alteration in original). Here, Plaintiff may have narrowed the ‘576 patent more than was necessary. That the Examiner suggested that “including” was permissible in the later-filed 15/718,470 application does not mean that Plaintiff can now broaden the scope of the ‘576 patent that it intentionally narrowed to overcome prior art.

Furthermore, Plaintiff’s 15/718,470 application itself suggests that “consisting of” in the ‘576 patent narrowed the scope of the mechanical fastener claim to only a mechanical fastener with a raised lip and mating portion. Otherwise, the 15/718,470 application would be redundant.

See Kao Corp. v. Unilever U.S., Inc., 441 F.3d 963, 973 n.5 (Fed. Cir. 2006) (“We note that subsequent to filing the ‘382 Patent, Kao filed a separate application ‘with claims specifically directed to salts of the copolymers claimed in the ‘382 patent.’ If Kao had intended to claim salt forms of the copolymer in the ‘382 Patent, the subsequent patent application would have been superfluous.”) (internal citation omitted).

Plaintiff’s reliance on *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004), is misguided. In *In re Crish*, one of the claims at issue was a “purified oligonucleotide comprising at least a portion of the nucleotide sequence of SEQ ID NO:1, wherein said portion consists of the nucleotide sequence from 521 to 2473 of SEQ ID NO:1, and wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity.” *Id.* at 1254 (emphasis added). The court concluded that the use of the transition term “comprising” allowed for the specified gene sequence and “other portions” of nucleotides found in the plasmid, but the court did not allow the claim to extend to a nucleotide promoter sequence that was not the recited numbered sequence following the “consists of” transition. *Id.* at 1257 (“The reasonable interpretation of the claims containing both of the terms ‘comprising’ and ‘consists’ is that the term ‘consists’ limits the ‘said portion’ language to the subsequently recited numbered nucleotides, but the earlier term ‘comprising’ means that the claim can include that portion plus other nucleotides.”). Thus, the court held that the first word “comprising” was open ended, followed by “consisting of,” which was closed ended as to everything that followed it. More precisely, the phrase “wherein said portion of the nucleotide sequence of SEQ ID NO:1 has promoter activity” refers back to “said portion” which is limited by “consisting of.” *Id.* That construction is consistent with the Court’s construction of “consisting of” as a term that limits the mechanical fastener claim.

2. Step Two: Infringement

To carry its burden with respect to the second step of summary judgment of patent infringement -- which requires a comparison of the properly construed claims to the accused product -- EMED must prove that “every limitation set forth in a claim must be found in an accused product, exactly.” *Southwall Techs., Inc.*, 54 F.3d at 1575.

a. Plug and Socket Fastener

The plug and socket fastener in the RMS devices defeats Plaintiff’s claim of infringement. Plaintiff cites forty-seven accused products as infringing in its infringement contentions. The accused products differ in construction only with respect to the needle gauge, the exposed length of the needle and the number of needles that are attached to a common delivery tube. Each of the accused products contains a pair of wings, a central body portion, a lip and a mating portion, a needle in the central body portion, *and* a second mechanical fastener consisting of a “cylindrical plug projecting from one wing that snap-fits into a corresponding socket located in the opposing wing to align and join the wings together in the closed position.” The plug of the accused products is located in the middle, not the perimeter, of a first wing. The socket is located in the middle, not the perimeter, of a second wing. As discussed above, the ‘576 patent does not claim any mechanical fastener beyond a mechanical fastener consisting of a “lip” and “mating portion.” To the extent that one of the mechanical fasteners of the accused products contains a socket and plug closure, it is not infringing.

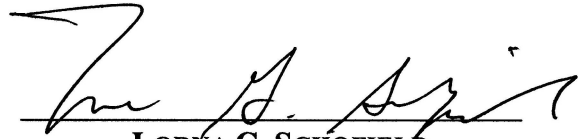
Even assuming that the lip and mating portion of the accused devices is infringing when considered in isolation (which Plaintiff argues and Defendant disputes), the challenged devices are not infringing because of the presence of the plug and socket fastener.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment is GRANTED.

The Clerk of Court is respectfully directed to close the motion at Docket Number 135 and close the case.

Dated: August 30, 2019
New York, NY



LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE